

Exhibit J

Docket No. IG5-4.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Katherine Gordon et al.
Serial No. : 07/426,464
Filed : October 20, 1989
For : TRANSGENIC ANIMALS SECRETING DESIRED
PROTEINS INTO MILK

Art Unit:
Examiner :

Commissioner of Patents and Trademarks
Washington, D.C. 20231

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AFFIDAVIT OF DR. JON GORDON

Sir:

I, Jon Gordon, the undersigned do hereby declare:

1. That I received my Ph.D. in 1978 and my M.D. in 1980 from Yale University and that I have spent the last ten years of my academic career in the detailed study of mammalian embryocogy and development, including the production of allophenic mice, the study of mammalian sex determination and gametogenesis the transfer of cloned genes into mouse embryos and analysis of expression of genes in transgenic mice. I have published in excess of 50 papers in these areas including an article in PNAS Vol. 77:7380 (1980) which reports on the first successful microinjection experiment giving rise to the first transgenic mouse.

2. That I am not related to Dr. Katherine Gordon, an inventor of the above captioned case;

3. That I am fully familiar with U.S. Serial No. 109,922, the parent of the above captioned continuation case and the Final Office Action dated May 1, 1989 issued in the 109,922 case wherein the claims were rejected under §35 U.S.C. 112 for lack of enablement due to unpredictability and under §35 U.S.C. 103 over Andres et al. and separately over Stewart et al., Leder et al. or Ross et al. taken in view of Overbeek et al., Ornitz et al., Hanahan, Palmiter or Khillan et al. taken in further view of Jones et al. or Qasba et al.;

4. That I am fully familiar with all of these references and the work upon which they report;

5. That given the state of the art in the field of transgenic animals and cloning techniques at the time the application was originally filed (April 9, 1986) in combination with the disclosure of the application, that the invention as claimed was not only fully enabled but that the generation of such transgenic animals producing proteins under the control of milk specific promoters and obtaining secretion into the milk was predictable;

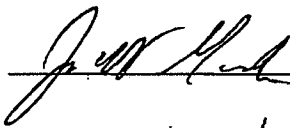
6. That subsequent work by a number of investigators, including that by the inventors, substantiated both the enablement and the predictability of such transgenic animals secreting desired proteins into their milk under the control of milk specific promoters because no additional unexpected difficulties requiring further inventive contribution or undo experimentation was necessitated in order to achieve such results;

7. That I am in disagreement with the statements made in the Final Office Action with respect to the allegations that the invention is obvious in view of the cited references because the invention represents not only a new method for producing proteins, but also provides an entirely new purpose for constructing a transgenic animal which is quite distinct from the specifics and the objections of the references;

8. That in particular, a critical aspect of the invention is not so much to direct expression to breast or mammary tissue but rather to so direct expression and obtain release of the protein from the mammary gland into the milk and that this advance is not shown by Andres et al. or any of the other cited references nor do I believe such references to make this novel concept obvious;

9. That I believe the application represents a novel notion to employ transgenically produced animals as a means for producing proteins and that this has not been disclosed or made obvious by any combination of the references cited by the Patent Office.

I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon and that all statements made herein of my knowledge are true and that all statements made on information are believed to be true.

By: 
Date: 3/28/91